DETAILED ACTION

Response to Amendment

Examiner acknowledges the reply filed 6/25/2009 in which claims 16 and 23 were amended. Currently claims 1-24 are pending for examination with claims 1-15 withdrawn from a previous election restriction.

Information Disclosure Statement

The information disclosure statement (IDS) that was submitted on 7/23/2009 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner is considering the information disclosure statement.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 16 and 23-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Cudahy et al. (USPN4,8956,161). Cudahy et al. discloses a transportable data module and display unit.

Regarding claims 16 and 23-24, Cudahy et al. discloses a device and method for monitoring a patient during a medical procedure in a medical care facility comprising (cols 1-2) the steps of: a) locating the patient in a first location (bedside) of the medical care facility and connecting to the patient at least one sensor (col 2, ln 40-50) for monitoring at least one physiological parameter of the patient; b) providing a first

housing having a first microprocessor-based patient unit (20) having at least one first connection point (34) for receiving input signals from the at least one sensor and at least one second connection point (52) for outputting patient physiological parameters; c) inputting to the first microprocessor-based patient unit physical attributes of the patient (Figure 1, col 2, ln 30-60); d) creating a patient record (col 2, ln 50-60); and e) locating the patient in a second location of the medical care facility (col 4, ln 25-60, transport or movement to long term care room), connecting the at least one second connection point to a second housing (portable unit 24) having a second microprocessor-based procedure unit (24), and performing a medical procedure on the patient using the first microprocessor- based patient unit and the second microprocessor-based procedure unit (Figures 1-4, cols 1-2).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 17-18 are rejected under 35 U.S.C. 102(e) as being anticipated by Cudahy et al. (USPN4,8956,161) in view of Thompson (USPN6,453,195). Cudahy et al. discloses the claim limitations as described above except for the drug delivery system.

However, Thompson discloses a closed loop drug delivery system and remote management thereof.

Regarding claims 17-18, Thompson discloses a method and device for monitoring a patient and delivering at least one drug during a medical procedure (Figure 3) comprising the steps of: in a first location (OR) connecting to the patient at least one sensor (238, 240) for monitoring at least one physiological parameter of the patient (col 6, Figure 4); providing a first housing having a first microprocessor-based (10) patient unit having at least one first connection point (236) for receiving input signals from the at least one sensor and at least one second connection point for outputting patient physiological parameters (23); inputting to the first microprocessor-based patient unit physical attributes of the patient; creating a patient record (col 2, ln 50-60, col 8, ln 45-65, col 13, ln 35-50); connecting the at least one second connection point (21) to a second housing having a second microprocessor-based procedure unit (20) and performing a medical procedure (drug delivery) on the patient in a second location (during standard doctors office visit, or ambulation) further consisting of the first microprocessor-based patient unit and the second microprocessor-based procedure unit (Figures 1-7) (cols 1-4).

At the time of the invention, it would have been obvious to use the system of Thompson with the system of Cudahy et al. in order to provide a drug delivery system

coupled to a monitoring system to aid with patient care. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Thompson (cols 1-2).

Claim Rejections - 35 USC § 103

Claims 19-22 are rejected under 35 U.S.C 103(a) as being unpatentable over Cudahy et al. (USPN4,8956,161) in view of Thompson (USPN6,453,195) in further view of Hickle (USPN6,453,195). The modified Cudahy et al. meets the claim limitations as described above except for the IV tube drug delivery device and oxygen therapy.

However, Hickle teaches an apparatus and method for providing conscious patient relief from pain during surgical procedures.

Regarding claims 19-22, Hickle teaches a method for monitoring a patient comprising connecting to the patient a plurality of sensors (12a) for monitoring at least physiological parameter of a patient (col 10, ln 35-55) having at least connection point and receiving signals to a first microprocessor (14) based patient unit and at least one second connection point (connection points between the processors shown in Figure 4A) for outputting patient physiological parameters, creating a patient record through an interface (35) and remote (45) and printer (37), providing a primed drug delivery system (142) in fluid communication with the patient controlled by the second microprocessor (2a) through a second connection points from the primary controller (14) and upon termination of the medical procedure, removing the connection points to the patient and controllers (Figures 1-18). Hickle further discloses the step of providing oxygen to a

patient (col 3 ln 50-70 and col 4, ln 1-15), querying a patient for a level of consciousness (col 4, ln 45-55), and the step of the patient activating a response (305) device (col 9) (see summary of invention, Figures 1-23A).

At the time of the invention, it would have been obvious to add the fluid pump and oxygen delivery to aid in a therapeutic drug delivery by a different delivery means for increased control over drug delivery. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Hickle (cols 1-2).

Response to Arguments

Applicant's arguments with respect to claims 16-24 have been considered but are moot in view of the new ground(s) of rejection necessitated by Applicant's amendment.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Koharski whose telephone number is 571-272-7230. The examiner can normally be reached on 5:30am to 2:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Date: 10/19/2009

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